K071059

510(k) SUMMARY

NAME OF FIRM:

DePuy Orthopaedics Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988
Establishment Registration Number: 1818910

510(K) CONTACT:

Kathy Harris
Director, Regulatory Affairs
Tel: (574) 372-7082
Fax: (574) 371-4987

NOV 0 9 2007

DATE PREPARED: October 20, 2007

TRADE NAME: DePuy SPA™ Porous Coated Proximal Sleeves

COMMON NAME: Femoral Proximal Sleeve

CLASSIFICATIONS:

21 CFR 888.3330: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis, Class III

21 CFR 888.3353: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, Class II

21 CFR 888.3358: Hip joint metal/polymer semi-constrained porous coated uncemented prosthesis, Class II

21 CFR 888.3310: Hip joint metal/polymer constrained cemented or uncemented prosthesis, Class II

DEVICE PRODUCT CODES: KWA, LZO, MEH, LPH, KWZ

SUBSTANTIALLY EQUIVALENT DEVICES:

S-ROM™ 135 Porous Coated Femoral Stem Collar, K860207 cleared August 6, 1986

Coated ZT™ Proximal Sleeve, K934412 cleared June 3, 1994

DEVICE DESCRIPTION:

The SPA Porous Coated Proximal Sleeve is a component of the S-ROM Total Hip Replacement System. It is a porous coated Titanium femoral component with an elliptical shape that matches the contour of the bone and a stepped exterior to maximize compressive stresses. Fixation of the proximal sleeve to the femur is achieved by biologic fixation via tissue in-growth into the porous coating.

INDICATIONS AND INTENDED USE:

The SPA Porous Coated Proximal Sleeve components of the S-ROM Total Hip System are indicated for use in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and nonunion of femoral fractures. Use of the prosthesis is also indicated for revision of previous hip arthroplasty and for patients with congenital hip dysplasia, protrusio acetabuli, slipped capital femoral epiphysis, and disability due to previous fusion.

The SPA Porous Coated Proximal Sleeves are intended for cementless use.

SUBSTANTIAL EQUIVALENCE:

The SPA Porous Coated Proximal Sleeve is identical in design, materials and manufacturing method to the S-ROM 135 Porous Coated Femoral Stem Collar, cleared in K860207 for cemented use only. The porous coating of the SPA Porous Coated Sleeve is identical to the porous coating used on the Coated ZT Proximal Sleeve, cleared in K934412 for cementless use. Based on these similarities, DePuy believes that the SPA Porous Coated Proximal Sleeve is substantially equivalent to the referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 9 2007

DuPuy Orthopaedics, Inc.
% Ms. Kathy Harris
Director, Regulatory Affairs
700 Orthopaedic Drive
Warsaw, IN 46581-0988

Re: K071059
Trade/Device Name: DePuy SPA™ Porous Coated Proximal Sleeves
Regulation Number: 21 CFR 888.3330
Regulation Name: Single/multiple component metallic bone Fixation appliances and accessories
Regulatory Class: Class III
Product Code: LPH, MEH, LZO, and KWZ
Dated: October 23, 2007
Received: October 24, 2007

Dear Ms. Harris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buehler for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K071059

Device Name: DePuy SPA Porous Coated Proximal Sleeves

Indications for Use:

The SPA Porous Coated Proximal Sleeve components of the S-ROM Total Hip System are indicated for use in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and nonunion of femoral fractures. Use of the prosthesis is also indicated for revision of previous hip arthroplasty and for patients with congenital hip dysplasia, protrusio acetabuli, slipped capital femoral epiphysis, and disability due to previous fusion.

The SPA Porous Coated Proximal Sleeves are intended for cementless use.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bruce

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071059